

PATENT  
Attorney Docket No. 09617.0001-00000

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: )  
Kiyoshi ANDO et al. ) Group Art Unit: 1644  
Serial No.: 10/510,627 ) Examiner: Michail A. BELYAVSKYI  
Filed: June 20, 2005 ) Confirmation No.: 4183  
For: METHOD OF JUDGING LEUKEMIA, )  
PRE-LEUKEMIA OR ALEUKEMIC )  
MALIGNANT BLOOD DISEASE AND )  
DIAGNOSTIC THEREFOR )

**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**DECLARATION UNDER 37 C.F.R. § 1.801-1.809**  
**REGARDING DEPOSIT OF BIOLOGICAL MATERIALS**

I do hereby declare and state that:

1. On information and belief, the Applicants have, under the provisions of the Budapest Treaty, deposited viable cultures of the KM2142 hybridoma producing monoclonal KM2142 antibody, the KM2804 hybridoma producing monoclonal antibody KM2804, and the KM2945 hybridoma producing monoclonal antibody KM2945 at the International Patent Organism Depositary (IPOD), National Institute of Advanced Industrial Science and Technology (AIST), AIST Tsukuba Central 6, 1-1, Higashi 1-Chome, Tsukuba-shi, Ibaraki-ken 305-8566, Japan, on February 26, 2002. The accession numbers for these deposits of hybridomas producing monoclonal

antibodies KM2142, KM2804, and KM2945 are FERM BP-7922, FERM BP-7923, and FERM BP-7924, respectively. Copies of the FERM BP-7922, FERM BP-7923, and FERM BP-7924 deposit receipts (both the Japanese form and the English translation) are attached as Appendix B.

2. On information and belief, the cultures were deposited under conditions which insure that access to the cultures will be available to persons determined by the Commissioner to be entitled thereto under 37 C.F.R. § 1.14 and 35 U.S.C. § 122.

3. Upon issuance of a patent on the above-identified patent application, or continuation applications thereof, any restriction as to the public availability of the deposits will be irrevocably removed, and the deposits will be replaced should the depository be unable to distribute a sample upon a proper request, during the enforceable life of the patent, or the period of five years after the last public request for the deposits, whichever period is longer.

4. The undersigned further declares that all statements made herein on their own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this document or any patent issuing thereon.

DATE: June 30, 2008

  
Masanori Hirota

## **APPENDIX B**

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

[特許手続上の微生物の寄託の国際的承認  
に関するブダペスト条約]

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

下記国際寄託当局によって規則7.1に従い  
発行される。

原寄託についての受託証

issued pursuant to Rule 7.1 by the  
INTERNATIONAL DEPOSITORY AUTHORITY  
identified at the bottom of this  
page.

氏名（名称） 協和醸酵工業株式会社  
取締役社長 平田 正 殿  
寄託者 あて名 〒 東京都千代田区大手町一丁目6番1号

|                                                                                                                                                                                                                                                                                                                                                                                           |                         |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--|
| 1. 微生物の表示                                                                                                                                                                                                                                                                                                                                                                                 |                         |  |
| (寄託者が付した識別のための表示)<br>KM2142                                                                                                                                                                                                                                                                                                                                                               | (受託番号)<br>FERM BP- 7922 |  |
| 2. 科学的性質及び分類学上の位置                                                                                                                                                                                                                                                                                                                                                                         |                         |  |
| 1欄の微生物には、次の事項を記載した文書が添付されていた。<br><br>■ 科学的性質<br>■ 分類学上の位置                                                                                                                                                                                                                                                                                                                                 |                         |  |
| 3. 受領及び受託                                                                                                                                                                                                                                                                                                                                                                                 |                         |  |
| 本国際寄託当局は、平成14年2月26日（原寄託日）に受領した1欄の微生物を受託する。                                                                                                                                                                                                                                                                                                                                                |                         |  |
| 4. 移管請求の受領                                                                                                                                                                                                                                                                                                                                                                                |                         |  |
| 本国際寄託当局は、 年 月 日（原寄託日）に1欄の微生物を受領した。<br>そして、 年 月 日に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。                                                                                                                                                                                                                                                                                                           |                         |  |
| 5. 国際寄託当局                                                                                                                                                                                                                                                                                                                                                                                 |                         |  |
| <p>独立行政法人産業技術総合研究所 特許生物寄託センター</p> <p>International Patent Organism Depository<br/>Name: National Institute of Advanced Industrial Science and Technology</p> <p>センター長 小松 泰彦<br/>Dr. Yasuhiko Komatsu Director</p> <p>あて名：日本国茨城県つくば市東1丁目1番地1 中央第6（郵便番号 305-8566）<br/>AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi,<br/>Ibaraki-ken 305-8566 Japan</p> <p>平成14年(2002) 2月26日</p> |                         |  |

## INTERNATIONAL FORM

(Translation)

BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF  
MICROORGANISMS FOR THE PURPOSES  
OF PATENT PROCEDURE

## RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1 by the  
INTERNATIONAL DEPOSITORY AUTHORITY  
identified at the bottom of this page.

## TO DEPOSITOR:

Name: KYOWA HAKKO KOGYO Co., Ltd.  
Representative: Tadashi Hirata  
Address: 6-1, Otemachi 1-chome, Chiyoda-ku, Tokyo

|                                                                                                                                                                                                                                              |                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| 1. IDENTIFICATION OF MICROORGANISM                                                                                                                                                                                                           |                                   |
| Identification Reference Given by the Depositor:<br>KM2142                                                                                                                                                                                   | Accession Number:<br>FERM BP-7922 |
| 2. A SCIENTIFIC DESCRIPTION AND/ OR PROPOSED TAXONOMIC POSITION                                                                                                                                                                              |                                   |
| The microorganism identified under 1. above was accompanied by a document stating the following item(s).<br><input checked="" type="checkbox"/> A Scientific Property<br><input checked="" type="checkbox"/> Taxonomic Position              |                                   |
| 3. RECEIPT AND ACCEPTANCE                                                                                                                                                                                                                    |                                   |
| This International Depository Authority accepts the microorganism identified under 1. above, which was received on February 26, 2002 (date of the original deposit).                                                                         |                                   |
| 4. RECEIPT OF REQUEST FOR TRANSFER                                                                                                                                                                                                           |                                   |
| This International Depository Authority received the microorganism under 1. above on _____ (date of the original deposit), and received on _____, a request for transfer from the original deposit to the deposit under the Budapest treaty. |                                   |
| 5. INTERNATIONAL DEPOSITORY AUTHORITY                                                                                                                                                                                                        |                                   |
| Name: International Patent Organism Depository<br>National Institute of Advanced Industrial Science and Technology                                                                                                                           |                                   |
| Representative: Dr. Yasuhiko Komatsu, Director (sealed)                                                                                                                                                                                      |                                   |
| Address: AIST Tsukuba Central 6, 1-1, Higashi 1-chome, Tsukuba-shi,<br>Ibaraki 305-8566 Japan                                                                                                                                                |                                   |
| Date: February 26, 2002                                                                                                                                                                                                                      |                                   |

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

[特許手続上の微生物の寄託の国際的承認  
に関するブダペスト条約]

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氏名（名称） 協和醸酵工業株式会社  
                  取締役社長 平田 正 殿  
寄託者 あて名 〒 東京都千代田区大手町一丁目6番1号

|                                                                                                                                                                                                                                                                                                                                                                                      |                         |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| 1. 微生物の表示                                                                                                                                                                                                                                                                                                                                                                            |                         |
| (寄託者が付した識別のための表示)<br>KM2804                                                                                                                                                                                                                                                                                                                                                          | (受託番号)<br>FERM BP- 7923 |
| 2. 科学的性質及び分類学上の位置                                                                                                                                                                                                                                                                                                                                                                    |                         |
| 1欄の微生物には、次の事項を記載した文書が添付されていた。<br><br>■ 科学的性質<br>■ 分類学上の位置                                                                                                                                                                                                                                                                                                                            |                         |
| 3. 受領及び受託                                                                                                                                                                                                                                                                                                                                                                            |                         |
| 本国際寄託当局は、平成14年2月26日（原寄託日）に受領した1欄の微生物を受託する。                                                                                                                                                                                                                                                                                                                                           |                         |
| 4. 移管請求の受領                                                                                                                                                                                                                                                                                                                                                                           |                         |
| 本国際寄託当局は、 年 月 日（原寄託日）に1欄の微生物を受領した。<br>そして、 年 月 日に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。                                                                                                                                                                                                                                                                                                      |                         |
| 5. 国際寄託当局                                                                                                                                                                                                                                                                                                                                                                            |                         |
| <p>独立行政法人産業技術総合研究所 特許生物寄託センター</p> <p>International Patent Organization Depository<br/>Name: National Institute of Advanced Industrial Science and Technology</p> <p>センター長 小松 泰彦<br/>Dr. Yasuhiko Komatsu</p> <p>あて名：日本国茨城県つくば市東1丁目1番地1 中央第6（郵便番号 305-8566）<br/>AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi,<br/>Ibaraki-ken 305-8566 Japan</p> <p>平成14年(2002) 2月26日</p> |                         |

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(Translation)

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Name: KYOWA HAKKO KOGYO Co., Ltd.  
Representative: Tadashi Hirata  
Address: 6-1, Otemachi 1-chome, Chiyoda-ku, Tokyo

|                                                                                                                                                                                                                                              |                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| 1. IDENTIFICATION OF MICROORGANISM                                                                                                                                                                                                           |                                   |
| Identification Reference Given by the Depositor:<br>KM2804                                                                                                                                                                                   | Accession Number:<br>FERM BP-7923 |
| 2. A SCIENTIFIC DESCRIPTION AND/ OR PROPOSED TAXONOMIC POSITION                                                                                                                                                                              |                                   |
| The microorganism identified under 1. above was accompanied by a document stating the following item(s).<br><input checked="" type="checkbox"/> A Scientific Property<br><input checked="" type="checkbox"/> Taxonomic Position              |                                   |
| 3. RECEIPT AND ACCEPTANCE                                                                                                                                                                                                                    |                                   |
| This International Depository Authority accepts the microorganism identified under 1. above, which was received on February 26, 2002 (date of the original deposit).                                                                         |                                   |
| 4. RECEIPT OF REQUEST FOR TRANSFER                                                                                                                                                                                                           |                                   |
| This International Depository Authority received the microorganism under 1. above on _____ (date of the original deposit), and received on _____, a request for transfer from the original deposit to the deposit under the Budapest treaty. |                                   |
| 5. INTERNATIONAL DEPOSITORY AUTHORITY                                                                                                                                                                                                        |                                   |
| Name: International Patent Organism Depository<br>National Institute of Advanced Industrial Science and Technology<br>Representative: Dr. Yasuhiko Komatsu, Director (sealed)                                                                |                                   |
| Address: AIST Tsukuba Central 6, 1-1, Higashi 1-chome, Tsukuba-shi,<br>Ibaraki 305-8566 Japan                                                                                                                                                |                                   |
| Date: February 26, 2002                                                                                                                                                                                                                      |                                   |

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特許手続上の微生物の寄託の国際的承認  
に関するブダペスト条約

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取締役社長 平田 正 殿  
寄託者 あて名 千  
東京都千代田区大手町一丁目6番1号

1. 微生物の表示

（寄託者が付した識別のための表示）  
KM2945

（受託番号）  
FERM BP- 7924

2. 科学的性質及び分類学上の位置

1欄の微生物には、次の事項を記載した文書が添付されていた。

- 科学的性質
- 分類学上の位置

3. 受領及び受託

本国際寄託当局は、平成 14 年 2 月 26 日（原寄託日）に受領した1欄の微生物を受託する。

4. 移管請求の受領

本国際寄託当局は、 年 月 日（原寄託日）に1欄の微生物を受領した。  
そして、 年 月 日に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。

5. 国際寄託当局

独立行政法人産業技術総合研究所 特許生物寄託センター

名 称： National Institute of Advanced Industrial Science and Technology  
International Patent Organization



センター長 小松 泰彦  
Dr. Yasuhiko Komatsu

あて名： 日本国茨城県つくば市東1丁目1番地1 中央第6（郵便番号 305-8566）  
AIST Tsukuba Central 6, 1-1, Higashi 1-Chome Tsukuba-shi,  
Ibaraki-ken 305-8566 Japan

平成14年(2002) 2月26日

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Name: KYOWA HAKKO KOGYO Co., Ltd.  
Representative: Tadashi Hirata  
Address: 6-1, Otemachi 1-chome, Chiyoda-ku, Tokyo

## 1. IDENTIFICATION OF MICROORGANISM

|                                                            |                                   |
|------------------------------------------------------------|-----------------------------------|
| Identification Reference Given by the Depositor:<br>KM2945 | Accession Number:<br>FERM BP-7924 |
|------------------------------------------------------------|-----------------------------------|

## 2. A SCIENTIFIC DESCRIPTION AND/ OR PROPOSED TAXONOMIC POSITION

The microorganism identified under 1. above was accompanied by a document stating the following item(s).

A Scientific Property  
 Taxonomic Position

## 3. RECEIPT AND ACCEPTANCE

This International Depository Authority accepts the microorganism identified under 1. above, which was received on February 26, 2002 (date of the original deposit).

## 4. RECEIPT OF REQUEST FOR TRANSFER

This International Depository Authority received the microorganism under 1. above on \_\_\_\_\_ (date of the original deposit), and received on \_\_\_\_\_, a request for transfer from the original deposit to the deposit under the Budapest treaty.

## 5. INTERNATIONAL DEPOSITORY AUTHORITY

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National Institute of Advanced Industrial Science and Technology

Representative: Dr. Yasuhiko Komatsu, Director (sealed)

Address: AIST Tsukuba Central 6, 1-1, Higashi 1-chome, Tsukuba-shi,  
Ibaraki 305-8566 Japan

Date: February 26, 2002